



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

Mr. G. P. Georges, III
Research and Development
Nephro-Tech, Inc.
P.O. Box 14703
Lenexa, Kansas 66285

FEB 10 1998

0557 '98 MAR 24 P2:42

Dear Mr. Georges:

This is in response to your letter of November 19, 1997 to the Food and Drug Administration (FDA) pursuant to 21 USC 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act). Your submission states that Nephro-Tech, Inc. is making the following statements, among others, for the products MagneBind 200 and MagneBind 300:

"The New Standard in Phosphate Binding"

"With lower amounts of calcium¹"

"No risk of aluminum toxicity^{2,3}"

"Well tolerated^{1,5}"

"With the ability to use higher doses of calcitriol¹"

"...oral supplementation with magnesium and calcium can reduce absorption of dietary phosphate."

21 USC 343(r)(6) requires that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for your products, including the citations that comprise a part of the statement, suggest that they are intended to treat, prevent, or mitigate disease, namely hyperphosphatemia in renal dialysis patients. These claims do not meet the requirements of 21 USC 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 USC 321(g)(1)(B), and that they are subject to regulation under the drug provisions of 21 USC 321. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely yours,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET 130

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, Kansas City District Office, Compliance Branch, HFR-SW340

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO, JGordon)

HFS-456 (file)

HFS-450 (r/f, file, OSN#56511)

HFD-310 (BWilliams)

HFD-314 (Aronson)

HFS-600 (Reynolds)

HFS-605 (Bowers)

GCF-1 (Nickerson, Dorsey)

r/d:HFS-456:RMoore:2/4/98

init:HFD-310:BWilliams:2/5/98

Revised per GCF-1:DDorsey:2/5/98

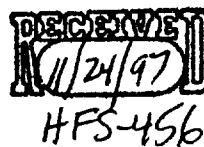
f/t:rjm:HFS-456:2/5/98:55845.adv:disc25

NEPHRO-TECH, INC.

P.O. Box 14703 • Lenexa, KS 66285

November 19, 1997

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St. SW
Washington, DC 20204



In compliance with the Dietary Supplement Health and Education Act of 1994, I am hereby notifying the Office of Special Nutritionals, Center for Food Safety and Applied Nutrition, Food and Drug Administration of NEPHRO-TECH, Inc.'s marketing of MagneBind™, a dietary supplement. MagneBind™ is marketed as a binder of dietary phosphate which is a function claim. I have provided labelling and our promotional material in triplicate as required.

If you have any further questions, please feel free to call me at 913-248-8808.

Sincerely,

NEPHRO-TECH, INC.


G. P. Georges, III
Research & Development



55845

The Phosphate Magnets

MAGNEBIND™ 200 and MAGNEBIND™ 300

are dietary supplements that combine the phosphate binding power of magnesium carbonate^{1,2,3} with calcium acetate⁴.

The New Standard In Phosphate Binding

→ With lower amounts of calcium¹

→ No risk of aluminum toxicity^{2,3}

→ Well tolerated^{1,5}

→ With the ability to use higher doses of calcitriol¹

#55845
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11/24/97
#FS-456



MEDICAID APPROVED*

Call 1-800-879-4755

For more information or samples

NEPHRO-TECH, INC.

P.O. Box 14703 • Lenexa, KS 66285

150 Tablets

59528-1028-15

MAGNEBIND™ 200

Magnesium Carbonate 200mg Calcium Acetate 450mg

Dietary Supplement



Phosphate Binder

Del. by

NEPHRO-TECH, INC.

Lenexa, Kansas 66285

Nutritional Facts		
Serving Size 1 Tablet		
Amount Per Tablet	% Daily Value	
Calcium 114 mg	11.4%	
Magnesium 57 mg	19%	

Ingredients: Calcium acetate USP, magnesium carbonate USP, microcrystalline cellulose, calcium stearate, stearic acid.

Description: Each tablet contains calcium acetate 450mg and magnesium carbonate 200mg.

Directions: Swallow 1-3 tablets with meals, or as directed by physician.

Indications: MAGNEBIND™ 200 is a dietary supplement that binds dietary phosphate. By binding with dietary phosphate, oral supplementation with magnesium and calcium can reduce absorption of dietary phosphate.*

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

IMPORTANT: Do not use if inner seal is disturbed or missing.

RECEIVED
11/24/97
HFS-456

150 Tablets

59528-0508-15

MAGNEBIND™ 300

Magnesium Carbonate 300mg Calcium Acetate 300mg

Dietary Supplement



Phosphate Binder

Del. by

NEPHRO-TECH, INC.

Lenexa, Kansas 66285

Nutritional Facts		
Serving Size 1 Tablet		
Amount Per Tablet	% Daily Value	
Calcium 76 mg	7.6%	
Magnesium 85 mg	28.3%	

Ingredients: Calcium acetate USP, magnesium carbonate USP, microcrystalline cellulose, calcium stearate, stearic acid.

Description: Each tablet contains calcium acetate 300mg and magnesium carbonate 300mg.

Directions: Swallow 1-3 tablets with meals, or as directed by physician.

Indications: MAGNEBIND™ 300 is a dietary supplement that binds dietary phosphate. By binding with dietary phosphate, oral supplementation with magnesium and calcium can reduce absorption of dietary phosphate.*

* This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

IMPORTANT: Do not use if inner seal is disturbed or missing.

20 Tablets

59528-1028-00

MAGNEBIND™ 200

Magnesium Carbonate 200mg Calcium Acetate 450mg

Dietary Supplement



Phosphate Binder

Del. by

NEPHRO-TECH, INC.

Lenexa, Kansas 66285

Nutritional Facts		
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20 Tablets

59528-0508-00

MAGNEBIND™ 300

Magnesium Carbonate 300mg Calcium Acetate 300mg

Dietary Supplement



Phosphate Binder

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NEPHRO-TECH, INC.

Lenexa, Kansas 66285

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59528-456

Del, J.A., J. Kelber, K.Y. Narwood, K.S. Giles, E. Slatopolsky. Magnesium carbonate as a phosphate binder. A prospective, controlled, crossover study. *Kidney Int.* 1996; 49:163-167.

R. O'Donovan, D. Baldwin, M. Hammer, C. Moniz, V. Parsons. Substitution of aluminum salts by magnesium salts in control of dialysis hyperphosphataemia. *Lancet* 1986; i:880-882

V. Parsons, D. Baldwin, C. Moniz, J. Marsden, E. Ball, J. Rifkin. Successful control of hyperparathyroidism in patients on continuous ambulatory peritoneal dialysis using magnesium carbonate and calcium carbonate as phosphate binders. *Nephrol.* 1993; 63:379-383.

MS Sheikh, JA Maguire, M. Emmett, CA Santa Ana, MJ Micar, IG Schilter, JS Fordtran. Reduction of dietary phosphorus absorption by phosphorus binders. A theoretical in vitro and in vivo study. *J. Clin. Invest.* 1989; 83:66-71.

J. Kelber, E. Slatopolsky, J. Delmez. Acute effects of different concentrations of dialysate magnesium during high-efficiency dialysis. *Am. J. Kid. Dis* 1994; 24:453-460.

Here are the references at the bottom of the
leaflet

Give me a call if you have questions or need
more background.